



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Application of

Hans SACHSE

Serial No. 09/742,354

Filed: December 22, 2000

For: PROBE FOR SMALL INTESTINES

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Art Unit: 3763

Examiner: Ghafoorian

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Person Making Deposit Karen Stamper

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Date of Signature

October 27, 2003

Honorable Comm'r. of Patents
PO Box 1450
Alexandria, VA 22313-1450

BRIEF ON APPEAL

Sir:

This appeal is from the examiner's final rejection of April 22, 2003.

REAL PARTY IN INTEREST

The real party in interest is Dr. Hans Sacshe of Nürnberg, Germany.

RELATED APPEALS AND INTERFERENCES

To the best of the undersigned's knowledge, there are no related appeals or interferences within the meaning of 37 CFR 1.192(c).

STATUS OF CLAIMS

Claims 1-10 have been finally rejected, claims 11-13 have been withdrawn from

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consideration, and claims 14-17 have been allowed. A copy of these claims is appended hereto.

STATUS OF AMENDMENTS

Applicants last amended the claims on February 12, 2003. No amendments under 37 CFR 1.116 have been filed.

SUMMARY OF INVENTION

As set out in the specification and claims, the instant invention relates to a probe with a "steerable" tip which can be introduced into the small intestines through the esophagus and stomach. The probe has a guide stylet with a curved tip area and a tube. When the stylet is inserted into the tube, the flexibility of the stylet and tube are such that the shape of the guide stylet is substantially imparted on the tip area of the tube.

ISSUE

Is the subject matter of claims 1-10 anticipated by or obvious over, within the meaning of 35 U.S.C. 102 and 103, Ensminger et al. (U.S. 5,256,146) or Bowe (U.S. 2001/0039413)?

GROUPING OF CLAIMS

Claim 1 is an independent claim directed to a probe for the small intestines. Claims 2-13 depend from claim 1. Claims 11-13 have not been examined and thus applicants do not concede that they stand or fall with claims 1-10 and such issue is not before the Board. Claims 14-17 are directed to a process and do not stand or fall with claims 1-10.

ARGUMENT

Applicant/appellant submits that the invention of claims 1-10 is not anticipated nor rendered obvious by Ensminger et al. (U.S. 5,256,146) or Bowe (U.S. 2001/0039413).

"A claim is anticipated only if each and every element as set forth in the claim is found...in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Furthermore, the "elements must be arranged as required by the claim..." *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

Claims 1, 2, 5-7 and 10 stand rejected under 35 U.S.C. 102(b) as being anticipated by Ensminger et al. (US 5,256,146). Ensminger discloses an "anchoring wire 14" which comes out of a "catheter lumen 20," but this wire does not impart its shape on the lumen as required by the present claims. An important aspect of the present invention is the difference of the flexibility of the wall of the probe and the flexibility of the guide stylet so the shape of the guide stylet is substantially imparted on the tip area of the probe tube. With this feature, the probe can be more easily introduced into the body, in particular the small intestine. Ensminger does not disclose such a feature.

Claims 1, 3 and 8-10 stand rejected under 35 U.S.C. 102(e) as being anticipated by Bowe (US 2001/0039413). Initially, applicants note that US 2001/0039413 is a C-I-P application which does not have a filing date prior to that of the present application. Therefore, any new matter relative to its parent application 09/516,280 is not prior art with respect to the instant application. In any event, the "outer sleeve 100" of the Bowe probe is straight when it is brought into the body and always remains straight. In other

words, the outer sleeve is not more flexible in the tip area and the shape of a guide stylet is not imparted on the outer sleeve as required by the instant claims. Only the "sheath 118" (referenced as a stylet by the examiner) is curved. However, said sheath does not impart its shape on any probe tube, but rather comes out of the outer sleeve. Still further, Bowe's sheath 118 does not have an outlet opening.

To establish a *prima facie* case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or combine reference teachings. MPEP 2143.

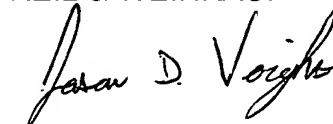
Claim 4 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Ensminger et al. or Bowe. The Examiner acknowledges that the cited references do not teach the limitation of claim 4 and the Examiner has not pointed out where the cited references suggest modifying the references to encompass such a limitation.

Therefore, the Examiner's rejections should be reversed.

Please charge any other shortage in fees due in connection with the filing of this paper to Deposit Account No. 11-0345. Please credit any excess fees to such deposit account.

Respectfully submitted,

KEIL & WEINKAUF

A handwritten signature in black ink, appearing to read "Jason D. Voight", written in a cursive style.

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APPENDIX

1. A probe for small intestines comprising
a probe tube (4) comprising a tip area (6) and a tip (2) having an outlet opening (1), and
a guide stylet (5) with a shape with a curved tip area (6'),
wherein the probe tube (4) and the guide stylet (5) each have a flexibility such that, in the absence of an external force, the shape of the guide stylet (5) is substantially imparted on the tip area (6) of the probe tube (4) when inserted therein.
2. The probe of claim 1, wherein the probe tube (4) is more flexible in the tip area (6) than in the rest of the tube.
3. The probe of claim 1, wherein the guide stylet has a spherically shaped tip (11).
4. The probe of claim 1, wherein the probe tube is thinner in the tip area (6) than in the rest of the probe tube (4).
5. The probe of claim 1, further comprising additional outlet openings (3) in the tip area (6).
6. The probe of claim 1, wherein the probe tube (4) is made from a plastic material.
7. The probe of claim 1, wherein the guide stylet (5) is made from a metal having a memory-effect.
8. The probe of claim 1, further comprising a termination (8) for connecting the guide stylet (5) to the probe tube (4).

9. The probe of claim 1, further comprising a fluid injection connector (7) on the probe tube (4).

10. The probe of claim 1, wherein the guide stylet (5) is sufficiently flexible so that it does not impart its shape on the probe tube (4) when the probe tube (4) is inserted in a human esophagus.

11. The probe of claim 1, wherein the probe tube comprises an outer tube and an inner stiffening tube (14) which does not extend into the tip area (6) of the probe tube (4).

12. The probe of claim 11, wherein the inner stiffening tube (14) is sufficiently rigid so that when the inner stiffening tube (14) and the guide stylet (5) are inserted into the probe tube (4), the guide stylet (5) does not substantially impart its shape on the inner stiffening tube (14).

13. The probe of claim 1, further comprising a sheath (13) on the probe tube (4) which is sufficiently rigid so that when the guide stylet (5) is inserted into the probe tube (4), the guide stylet (5) does not substantially impart its shape on the probe tube (4).

14. A process for delivering fluid to small intestines with a probe,
said probe comprising
a probe tube (4) comprising a tip area (6) and a tip (2) having an outlet opening (1), and

a guide stylet (5) with a shape with a curved tip area (6'),
wherein the probe tube (4) and the guide stylet (5) each have a flexibility such that, in

the absence of an external force, the shape of the guide stylet (5) is substantially imparted on the tip area (6) of the probe tube (4) when inserted therein

said process comprising the steps of

inserting the probe tube (4) into a patient's stomach by way of the patient's esophagus,

inserting the guide stylet (5) into the probe tube (4) thereby causing the shape of the guide stylet (5) to be substantially imparted on the tip area (6) of the probe tube (4),

inserting the tip (2) of the probe tube (4) into the patient's small intestines by way of the patient's pylorus, and

passing the fluid through a lumen (9) and the opening (1) of the probe tube.

15. The process of claim 14, further comprising the step of spraying X-ray contrast medium into the probe tube (4) prior to inserting the tip (2) of the probe tube (4) into the small intestines.

16. The process of claim 14, further comprising inserting a second straight stylet into the probe tube (4) prior to inserting the probe tube (4) into the stomach.

17. The process of claim 14, wherein the probe tube comprises an outer tube and an inner stiffening tube (14) which does not extend into the tip area (6) of the probe tube (4).



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October 27, 2003

Date of Deposit Karen Stamper

Person Making Deposit

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1. ☐ NOTICE OF APPEAL: Applicant hereby appeals to the Board of Appeals from the decision dated _____ of the Primary Examiner finally rejecting claims ____.
2. ☐ A check in the amount of \$____ is attached to cover the required extension of time fee.
3. ☒ BRIEF on appeal in this application is transmitted herewith.
4. ☐ An Oral Hearing is requested.
☐ The Oral Hearing fee of \$290.00 is enclosed.
5. ☒ Fee \$165.00 (**small entity**)
☒ Enclosed
6. ☒ The Commissioner is hereby authorized to charge any fees which may be further required, or credit any over payment to Account No. 11-0345. A duplicate copy of this sheet is attached.

Respectfully submitted,
KEIL & WEINKAUF

JDV/kas

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By Jason D. Voight
Jason D. Voight
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